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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,198	09/15/2003	Guenter Kirschner	0259-0417P	1390
2292 7590 01/08/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH WA 22040 0747			EXAMINER	
			MARX, IRENE	
FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER
			1651	
SHORTENED STATUTORY	PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		01/08/2007	FLECTRONIC	

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/08/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

	Application No.	Applicant(s)				
	10/663,198	KIRSCHNER ET AL.				
Office Action Summary	Examiner	Art Unit				
	Irene Marx	1651				
The MAILING DATE of this communication app Period for Reply	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filled after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filled, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 19 O	<u>ctober 2006</u> .					
2a)⊠ This action is FINAL. 2b)☐ This	action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-21</u> is/are pending in the application.						
4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-11 and 15-21</u> is/are rejected.	·					
7) Claim(s) is/are objected to.	•	\$3				
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate				
3) Information Disclosure Statement(s) (PTO/SB/08)	5) Notice of Informal P 6) Other:	atent Application				
Paper No(s)/Mail Date  U.S. Patent and Trademark Office	6)					
	tion Summary Pa	rt of Paper No./Mail Date 20061025				

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## **DETAILED-ACTION**

The amendment filed 10/19/06 is acknowledged. Claims 1-11 and 15-21 are being considered on the merits.

Claims 12-14 are withdrawn from consideration as directed to a non-elected invention.

The amendment presented fails to comply with the Revised Amendment Format CFR

1.121.

(c) Claims. Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered). See Rule 37 C.F.R. § 1.121.

Claims 20 and 21 are new claims which are indicated as "Currently amended". Correction is **required**.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20-21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for a phosphatidyl-L-serine sodium salt composition that is at least 95% pure. No basis or support is found for a product as

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claimed wherein phosphatidylcholine reactant that is completely converted to phosphatidyl-L-serine sodium salt.

Applicants have not indicated the location in the written disclosure that provides support or basis for the recitation.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 6 appear internally inconsistent in being directed to a sodium salt, yet the R1 moiety is hydroxyl.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 11, 15, 17-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Sakai (U.S. Patent No. 6,117,853)

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The claims are drawn to a phosphatidyl-L-serine sodium salt composition suitable for use as a cosmetic or food additive having a fatty acid composition identical to that of soybean lecithin having a degree of peroxidation less than 5 produced by a certain process.

Sakai discloses a phosphatidyl-L-serine composition which contains phosphatidyl-L-serine sodium salt compositions having the same structure as claimed and which is recognized to be useful as a food additive or a pharmaceutical for oral administration. See, e.g., Example 1. Inasmuch as a sodium phosphate buffer is used, phosphatidyl-L-serine sodium salt is present at least to some extent.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the

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applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Claims 1, 3, and 5-6 are rejected under 35 U.S.C. 102(e) as being anticipated by De Tommaso (U.S. Patent No. 6,326,406)

The claims are drawn to a phosphatidyl serine sodium salt product having a fatty acid composition identical to that of soybean lecithin having a degree of peroxidation less than 5 produced by a certain process.

De Tommaso discloses a phosphatidyl-L-serine sodium salt produced chemically having a fatty acid composition identical to that of soybean lecithin and presumed to have a degree of peroxidation less than 5 which has the same structure as claimed produced inherently at least to some extent by the reaction of soybean lecithin with sodium glycocholate. (See, e.g.,col. 4, lines 41-49.).

E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-

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process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Claims 1, 4, 5, 6, are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Koch (http://www.jbc.org/cgi/reprint/3/1/53.pdf)

The claims are drawn to a phosphatidyl serine sodium salt product having a fatty acid composition identical to that of egg lecithin having a degree of peroxidation less than 5 produced by a certain process.

The cited reference discloses a phosphatidyl-L-serine sodium salt produced chemically having a fatty acid composition identical to that of egg lecithin and presumed to have a degree of peroxidation less than 5 which appears to be identical to the presently claimed product, since egg lecithin is treated with sodium salts, which inherently produces a phosphatidyl-L-serine sodium salt. (See, e.g., Table II).

In the alternative, even if the claimed products are not identical to the referenced products with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced products are likely to naturally possess the same characteristics of the claimed products particularly in view of the identical characteristics which they share. Thus the claimed product would have been obvious to those skilled in the art within the meaning of USC 103.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does

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not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

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Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1, and 4-6, are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brajtburg et al. (Antimicrobial Agents and Chemotherapy, Dec. 1990, p. 2415-2416)

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The claims are drawn to a phosphatidyl serine sodium salt product having a fatty acid composition identical to that of egg lecithin having a degree of peroxidation less than 5 produced by a certain process.

The cited reference discloses a phosphatidyl-L-serine sodium salt produced chemically having a fatty acid composition identical to that of egg lecithin and presumed to have a degree of peroxidation less than 5 which appears to be identical to the presently claimed product, since egg lecithin is treated with sodium salts, which inherently produces a phosphatidyl-L-serine sodium salt. (See, e.g., page 2415, paragraph 3).

In the alternative, even if the claimed products are not identical to the referenced products with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced products are likely to naturally possess the same characteristics of the claimed products particularly in view of the identical characteristics which they share. Thus the claimed product would have been obvious to those skilled in the art within the meaning of USC 103.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

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Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1-11 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai taken with De Ferra et al., Horrobin (U.S. Patent No. 5,466,841), Puricelli, Chemical Land 21 and Kurihara et al. (U.S. Patent No. 5,785,984).

Sakai et al. is discussed above. Even though the reference does not explicitly recite the sodium salt of phosphatidyl serine, it clearly recognizes that at least the sodium salts of lysophosphatidyl serine. In addition, De Ferra discloses the conversion of calcium salts to any other salt using conventional techniques. which strongly suggests that one of ordinary skill in the art recognizes that various salts of phosphatidyl serine, including sodium salts, were well known in the art at the time the claimed invention was made (See, e.g., col. 4, lines 30-33).

The reference differs from the claimed invention in that no cosmetics or pharmaceutical preparations containing phosphatides are disclosed. However, each of Horrobin (U.S. Patent No. 5,466,841), Puricelli, and Chemical Land 21 discloses pharmaceutical compositions which are pharmaceuticals useful as cosmetics and/or food additives. See, e.g., Horrobin, See, e.g., col. 13, line 45 et seq. and claim 4; Puricelli, pages 3-4 and Examples; and Chemical Land 21, General Description and Applications..

In addition Kurihara et al. disclose edible products containing soybean lecithin (See, e.g., Examples 4-5) or phosphates, (See, e.g., Examples 21, 23, 27, 29). Kurihara et al. also

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demonstrates that various forms of providing pharmaceuticals and/or cosmetics are old and well-known in the art. See, e.g., col. 7-9.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of Sakai, if necessary, as suggested by Art Unit: 1651

De Ferra et al. for use in cosmetics and pharmaceuticals by adding suitable carriers and providing the compositions in various forms, as suggested by the teachings of Sakai, De Ferra et al. and Kurihara et al., for the expected benefit of providing compositions which are orally administratable and that have favorable organoleptic as well as superior pharmaceutical and cosmetic properties.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicants' arguments are moot in view of the new grounds of rejection.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Them man Irene Marx **Primary Examiner** Art Unit 1651